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From: Skinner, Sakinda [SSkinner@KelleyDrye.com] on behalf of McMahon, Kathryn [KMcMahon@KelleyDrye.com]

Sent: Tuesday, March 31, 2009 4:22 PM

To: NIOSH Docket Office (CDC)

Cc: McMahon, Kathryn; Deborah Proctor

Subject: 144 - NIOSH Criteria Document Update: Occupational Exposure to Hexavalent Chromium

Attachments: Cover Letter re- 144- NIOSH Criteria Document on Hex Chrome.doc; EXHIBIT I - SSINA Comments re- 144 NIOSH Criteria Document on Hex Chrome.doc

Dear Sir/Madam:

Please find attached a Cover letter and Comments regarding 144 - NIOSH Criteria Document Update: *Occupational Exposure to Hexavalent Chromium*. Should you have any questions or concerns please feel free to contact us. Thank you for the opportunity to provide comments on NIOSH's proposed action related to hexavalent chromium.

Respectfully submitted,

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March 31, 2009

National Institute for Occupational Safety & Health
NIOSH Docket Office
NIOSH Mailstop C-34
Robert A. Taft Lab
4676 Columbia Parkway
Cincinnati, Ohio 45226

Re: 144 - NIOSH Criteria Document Update: Occupational Exposure to Hexavalent Chromium

Dear Sir/Madam:

The following comments, attached hereto as Exhibit I, are submitted on behalf of the Specialty Steel Industry of North America (SSINA). SSINA is a trade association comprised of eleven companies engaged in the fully integrated manufacture and distribution of specialty metals in mill product form (sheet, strip, plate, billet, ingot, bar, rod, wire, etc.). Our customers use these materials to make end use items serving virtually all segments of the economy, including defense; aerospace; consumer products; electronics, computers and communications; automotive and transportation; energy generation and distribution; chemical processing; pharmaceuticals; oil and gas production, distribution and refining; food processing; medical devices, instrumentation and hardware, and others. The "specialty" nature of these materials refers to their unique chemistry and high tech processing requirements. The materials themselves include stainless steels, tool steels, electrical steels, and nickel alloys among others. SSINA members account for the majority of the specialty steel produced in the United States.

SSINA welcomes the opportunity to submit comments on the National Institute for Occupational Safety & Health (NIOSH) Criteria Document Update: *Occupational Exposure to Hexavalent Chromium.* SSINA recommends against the reduction of the Recommended Exposure Level (REL) from 1 $\mu g/m^3$ to 0.2 $\mu g/m^3$. SSINA submitted extensive comments and participated heavily in the Occupational Safety & Health Administration (OSHA) rulemaking on occupational exposures to hexavalent chromium, and detailed its position on both feasibility and health risk issues in the course of that rulemaking. SSINA believes that a REL of 0.2 $\mu g/m^3$ is both unnecessary to protect against health risk, as well as infeasible to meet for virtually all SSINA member companies and their customers.

SSINA urges NIOSH to consider the comments submitted herein. We appreciate the opportunity to provide comments on NIOSH's proposed action related to hexavalent chromium.

Sincerely,

________/s/___________

Kathryn McMahon-Lohrer
Counsel to the Specialty Steel Industry of North America

Exponent

March 31, 2009

Comments on Criteria Document Update For Occupational Exposure To Hexavalent Chromium: September 2008 External Review Draft

On behalf of the Stainless Steel Industry of North America, Exponent has reviewed the National Institute for Occupational Safety and Health (NIOSH) external review draft Criteria Document Update for Occupational Exposure to Hexavalent Chromium [Cr(VI)] and appreciates this opportunity to submit comments. The draft Criteria Document presents a new Recommended Exposure Limit (REL) of 0.2 $\mu g/m^3$ as an 8-hour TWA for a 40-hr week, which is associated with a one-in-one-thousand theoretical increased cancer risk for 45 years of occupational exposure to Cr(VI). The value was derived from NIOSH's risk assessment of the Baltimore cohort of chromate production workers (Park et al. 2004). This REL is reduced from the current value of 1 $\mu g/m^3$ and is 25 times lower than the current Permissible Exposure Limit (PEL) of 5 $\mu g/m^3$.

Exponent offers the following comments regarding this draft.

1 Recommendations for risk management should be based on exposure levels.

NIOSH's recommendations for risk management actions are not limited to exposures that exceed any specific level. Medical monitoring is recommended for all workers who incur any exposure to Cr(VI), regardless of the concentration or frequency of exposure. While medical monitoring of workers with Cr(VI) exposures may be the most desirable recommendation, given that resources are limited for monitoring, a recommendation that focuses medical monitoring on those workers with a relatively greater risk of health effects may be more rigorously followed and ultimately more effective. We suggest that the recommendations for medical monitoring be focused on workers with the greatest likely hazard based on exposure level, occupation, or industry with the most significant hazards.

On p. 141 of the Criteria Document, NIOSH states, "The employer should establish a medical monitoring program for all workers with occupational exposure to Cr(VI) compounds, including personnel involved with routine or emergency repair or maintenance." Recommendations for dermal exposure are to eliminate all dermal contact with Cr(VI). On p. 122 of the Criteria Document, NIOSH states, "In addition to limiting airborne concentrations of Cr(VI) compounds, NIOSH recommends that dermal exposure to Cr(VI) be prevented in the workplace to reduce the risk of adverse dermal health effects including irritation, ulcers, allergic contact dermatitis, and skin sensitization." Similarly, airborne monitoring and respirator use are recommended are for all exposures that exceed 0.2 $\mu g/m^3$—which will include virtually all Cr(VI)-exposed workers according to NIOSH's exposure survey (Section 2.5)—or if exposure concentrations are unknown (p. 135, Criteria Document). It would be more helpful if the Criteria Document provided the levels of exposure that have resulted in adverse health effects and offered recommendations for preventing exposures to those levels, or measures to reduce hazards. For example, the Document states that more than 1,000,000 workers are exposed to Cr(VI) in wet cement (page iv). In the EU, there is a limit of 2 mg/kg Cr(VI) in dry cement, and to reduce Cr(VI) levels, cement is manufactured with a reducing agent, typically ferrous sulfate. A similar recommendation for U.S. workers is more likely to reduce dermal effects than a recommendation to prevent all contact with Cr(VI), which would be difficult to implement or monitor.

In the new OSHA Rule for Cr(VI), OSHA requires that medical surveillance be provided to those employees who are experiencing signs or symptoms of adverse health effects associated with Cr(VI) exposure, or who are exposed in an emergency. In addition, OSHA stated that general industry, construction, and shipyard employers be required to provide medical surveillance for all employees exposed to Cr(VI) at or above the action level of 2.5 $\mu g/m^3$ for more than 30 days per year. A similar recommendation from NIOSH would more likely improve worker health.

As part of the medical monitoring program, NIOSH recommends periodic chest x-rays of workers exposed to Cr(VI), due to the risk of lung cancer. However, the current scientific literature and other agencies, including the National Cancer Institute (NCI) and the U.S. Preventive Services Task Force, state that the benefit of screening for lung cancer is uncertain. The NCI evaluated a number of randomized, controlled studies and case-control studies investigating the benefit of chest x-rays and sputum cytology as screens for lung cancer. The NCI concluded that there is no good evidence that screening for lung cancer using chest x-ray or sputum cytology can reduce lung cancer mortality. It states, "Uncertainty in interpretation of results from completed studies has led to conflicting positions in the medical community and confusion in populations at risk regarding the value of chest x-ray screening" (NCI 2009a). NCI further states, regarding the risk/benefit analysis of chest x-ray and/or sputum cytology as screening tools for lung cancer, that "Based on solid evidence, screening would lead to false-positive tests and unnecessary invasive diagnostic procedures and treatments" (NCI 2009b).

The U.S. Preventive Services Task Force examined the evidence evaluating screening for lung cancer with chest radiography, sputum cytologic examination, and low-dose computed tomography (CT), to update its recommendation on lung cancer screening (Humphrey et al. 2004). Humphrey et al. (2004) state, "No major medical professional organization currently recommends screening for lung cancer. The U.S. Preventive Services Task Force (USPSTF) gave lung cancer screening a grade D recommendation in both 1985 and 1996, meaning that there were fair quality data to recommend against screening for lung cancer based largely on 3 negative trials conducted in the United States in the 1970s." In its present analysis, published in the year 2004, Humphrey et al. conclude that current data do not support screening for lung cancer with any method.

In summary, Exponent recommends that NIOSH provide risk management strategies that are based on an exposure level, similar to the OSHA Rule, which recommends medical monitoring for specific conditions or upon attaining certain exposure levels. Further, it is not likely that medical monitoring for lung cancer will reduce the risk of lung cancer mortality, and workers may increase the risk of adverse outcomes by participating in lung cancer medical monitoring programs.

2 NIOSH's risk assessment focuses on lung cancer findings for the chromate production industry and should consider risk to welders and the majority of workers with significant Cr(VI) exposure in the U.S.

The Criteria Document should address the disparity of findings regarding the lung cancer risk in the chromate production industry and that for welding. Welders are the most numerous occupation with significant Cr(VI) exposure, and it is questionable whether lung cancer risks from the historical chromate production industry, based on statistical models and cumulative dose from airborne concentrations, can be used to reasonable estimate risks for welders.

NIOSH states that its summary of lung cancer epidemiology is focused on those studies that provided exposure-response data and were published since the IARC update of 1990 (p. 39–40) or that were not reviewed previously by NIOSH [1975, 1980] (page 39, first paragraph). It is not clear why the discussion of cancer epidemiology in the draft Criteria Document is so limited, and we recommend referencing the OSHA risk assessment for the 2006 rule, (OSHA 2006). The Criteria Document sections that provide the discussion of lung cancer (4.1.1.1.1–4.1.1.1.4) primarily discuss lung cancer findings for the chromate production industry. However, the number of chromate production workers in the U.S. is extremely small (150, or <0.03% of all Cr(VI)-exposed workers in 2006) compared to the number of workers exposed by welding (269,379, or 48% of all Cr(VI)-exposed workers in the U.S. in 2006) (Criteria Document page 11). As such, greater effort should be devoted to describing the risk to welders.

Welders' exposures to Cr(VI), particularly stainless steel welders, far exceed the proposed and current RELs of 0.2 and 1 $\mu g/m^3$. Table 2-6 of the Criteria Document provides exposure data for welders that range from the limit of detection to 22 $\mu g/m^3$ and categorizes these exposures as Category 3 processes, with moderate difficulty to control to 1 $\mu g/m^3$. Further, relevant to the cohorts of welders studied for lung cancer risk, historical welding exposures have been much higher than that provided in Table 2-6. Historical welding exposures are summarized below.

- Exposures to Cr(VI) among welders vary considerably, depending on the welding process, metals being welded, and available ventilation. IARC (1990) conducted a review of Cr(VI) exposure levels among welders and reported the average range from their review of the industry. Cr(VI) exposure levels from stainless-steel welding varied widely, but most were less than 10 $\mu g/m^3$. In IARC's review, upper-bound exposures from stainless-steel welding were in the range of 400 to 1,500 $\mu g/m^3$.

- For the cohort of railway-track welders of stainless steel (Sjögren et al. 1987), median levels were estimated using data from a national survey of air pollution in stainless-steel welders (the survey was conducted 10 years prior to the research), to be a time-weighted average (TWA) of 110 μg CrO_3/m^3 (57 $\mu g/m^3$ measured as CrVI) for welding using coated electrodes, and 10 μg CrO_3/m^3 (5.2 $\mu g/m^3$ measured as CrVI) for gas-shielded welding. Peak levels were estimated to be 750 μg CrO_3/m^3 (390 $\mu g/m^3$ measured as CrVI) for welding with coated electrodes, and 440 μg CrO_3/m^3 (229 $\mu g/m^3$ measured as CrVI) for gas-shielded welding.

- For the Gérin et al. (1993) cohort of stainless steel welders, exposures were estimated to range from 5 to 120 $\mu g/m^3$.

- Page 51 of the Criteria Document provides a discussion of exposures to Cr(VI) from welding fumes among shipyard workers in Korea (Lee et al. 2002). Airborne concentrations range from approximately 1 to 500 $\mu g/m^3$. Although the authors characterize this exposure as "low level," and their conclusions are cited as such in the Criteria Document, it should be noted that these are not low exposures, especially when considering that the proposed REL is 0.2 $\mu g/m^3$, and these exposures are above the current REL of 1 $\mu g/m^3$. (NIOSH should also convert these exposure data from mg/m^3 to $\mu g/m^3$ to reduce confusion [page 51]).

Thus, while the levels of Cr(VI) exposure among welders are not as high as experienced in the historical Painesville chromate production plant, they are likely similar to that of the Baltimore plant. Although exposure misclassification is a concern with welding studies, giving the preponderance of the findings and the size of the cohorts studied, it is not reasonable to assume that the risk assessment for Cr(VI) developed from the chromate production industry and used for the proposed REL, is representative of the risk experienced by stainless-steel welders exposed to Cr(VI).

The Criteria Document states that "smaller particles, as in welding fume exposure (<0.5 µm) may be more efficiently reduced [to trivalent chromium] in the lungs than larger particles, such as those of the chromate dust exposure (>10 µm)" (page 35-36). We recommend that NIOSH more fully develop this potentially important observation and consider the kinetic differences in exposures experienced by different industries. This disparity may provide a plausible biological basis for the observed lower lung cancer risk among welders than among chromate production and pigment production workers. Specifically, tissue dose in the lung is likely to be a better dose measure than airborne concentration because of variability in the rate at which Cr(VI) is cleared from the lung. Particle size and solubility are two critical parameters to consider when evaluating exposure by industry.

Several studies of welders have been published that could be considered in the Criteria Document, because they inform the lung cancer risk assessment and are specifically relevant to the largest occupation with Cr(VI) exposures. Section 4.1.1.1.4 discusses the IARC European welders study (Simonato et al. 1991), in which no dose response was observed with Cr(VI) exposures. Further, Gérin et al. (1993) provides additional evaluations of this cohort to better describe a dose-response relationship using the available data. OSHA (2006) used the Gérin et al. (1993) in quantitative risk assessment; however, the lower bound of the 95% confidence interval included zero. Further, as discussed below, Moulin (1997) conducted a meta-analysis of welders and also determined that there is a no dose-response for Cr(VI) exposure and lung cancer risk among welders.

Finally, as noted in the Criteria Document (page 44), IARC (1990) states that there is *limited evidence* in humans for the carcinogenicity of welding fumes and gases. There is *inadequate evidence* in experimental animals for the carcinogenicity of welding fumes. The overall evaluation indicates that welding fumes are *possible carcinogens to humans* (Group 2B). It is important to compare these conclusions to IARC's (1990) conclusions regarding the chromate production industry—that "there is *sufficient evidence* in humans for the carcinogenicity of chromium[VI] compounds as encountered in the chromate production, chromate pigment production and chromium plating industries." On the basis of these data, and others, Cr(VI) is described as "*carcinogenic to humans* (Group 1)."

Because of the differences in carcinogenic potential between welders and historical chromate production workers, and because far more workers are welders than chromate production workers in the U.S., the Criteria Document should provide an expanded discussion of the epidemiology literature for welders, and to the extent feasible, should base the new proposed REL on welding data rather than on data for the chromate production industry. Other risk assessment tools such as physiologically based pharmacokinetic modeling and biologically-based dose response modeling could be used to increase the applicability of exposure in the historical chromate production industry to others, and specifically to welding.

Finally, Section 4.1.4, Cancer Meta-analyses, does not include the meta-analysis by Moulin (1997) of stainless-steel and mild-steel welders. Moulin (1997) combined the results of 18 case-control and 31 cohort studies of welders, and calculated relative risks (RRs) for lung cancer for all non-specified welding categories, shipyard welders, nonshipyard welders, mild-steel welders, and stainless-steel welders. The RR for mild-steel welders, who incur minimal to no Cr(VI) exposure, was the same as that for stainless-steel welders who have much higher Cr(VI) exposures. The RR for mild-steel welders was 1.50 (95% CI: 1.18–1.91, based on 137 cases), and the RR for stainless steel welders was 1.50 (95% CI: 1.10–2.05, based on 114 cases). These authors concluded that a 30% to 40% increase in the RR of lung cancer experienced by welders cannot be explained by exposure of stainless-steel welders to Cr(VI) or to nickel. These findings draw into serious question whether the lung cancer risk assessment of chromate production workers can be extrapolated to stainless-steel welders.

3 Conservative approaches were used to calculate the proposed REL and assess cancer risk.

NIOSH's proposed REL of 0.2 $\mu g/m^3$ is based on 45 years of continuous occupational exposure to Cr(VI) for 8 hours per day (40 hours per week), assuming a one-in-one-thousand theoretical lung cancer risk. It was based on NIOSH's risk assessment that employed a statistical modeling approach to predict potential risks for exposures at the proposed REL, which are not observed in the original epidemiological study (Gibb et al. 2000; Park et al. 2004). NIOSH has selected a very conservative approach to quantify risk as the basis for the proposed REL, and as noted above, there are uncertainties in extrapolating this risk assessment to other industries and exposure conditions. Dr. Herman Gibb acknowledged the uncertainty regarding risks to welders in his testimony regarding the OSHA draft PEL:

> "The epidemiologic studies of welders *** conducted to date have been limited in their ability to evaluate a lung cancer risk. It is conceivable that differences in exposure *** between [this industry] and the chromate production industry could lead to differences in cancer risk. Because there aren't adequate data with which to evaluate these differences, it is appropriate to compare the upper bounds [on risk] derived from the Gerin et al. *** [study] with those predicted from the chromate production workers to determine if they are consistent" (page 10194, first column, OSHA 2006).

The Rule continues to state that the maximum likelihood risk estimates based on the Gerin cohort were somewhat lower than those based on the Gibb and Luippold et al. cohorts, which suggests, according to Gibb's testimony, that the dose response is not consistent between these industries. Yet, OSHA continues that it believes the lower risk estimates from Gerin et al. may be explained by exposure misclassification. However, this conclusion is questionable, because arguably, there would be greater evidence of an increased lung cancer risk associated with Cr(VI) exposures among welders if the dose response for the historical chromate production industry was in fact representative of Cr(VI) exposures from welding.

Finally, there is one element of the discussion that is unclear and should be addressed further. While NIOSH uses the Gibb et al. (2000) study data as the basis for the REL due to the "high" quality of the exposure data, the evaluation also discounts the observation of a threshold for carcinogenicity identified in the Park and Stayner (2006) study—which was conducted with the same exposure data set (i.e., the Baltimore cohort)—on the basis of limitations of the exposure data in the low-dose range (page 95). It is unclear why uncertainties in the exposure data are applicable to evaluation of exposure thresholds but not the exposure data that is used as the basis of the proposed REL.

4 NIOSH's determinations of whether industry can meet the REL are not based on the new proposed REL of 0.2 $\mu g/m^3$, and it is reasonable to conclude that virtually no occupations or industries will be able to meet the proposed REL.

NIOSH's evaluation of whether industry can meet the proposed REL of 0.2 $\mu g/m^3$ is based on comparisons of its 1999–2001 occupational exposure survey results (Blade et al. 2007) to the current REL of 1 $\mu g/m^3$ (Criteria Document, p. 12). In this evaluation, NIOSH conducted a Cr(VI) field research study consisting of industrial-hygiene and engineering surveys at 21 selected sites representing a variety of industrial sectors, operations, and processes. This study characterized workers' exposures to Cr(VI)-containing airborne particulates and evaluated existing technologies for controlling these exposures. NIOSH organized all the gathered data on occupational exposures into four categories to describe the difficulty in meeting the current REL of 1 $\mu g/m^3$. These categories are described based on the relative difficulty of improving control effectiveness to an adequate degree to achieve the current REL. The four categories were as follows: (1) those with minimal worker exposures to Cr(VI) in air, (2) those with workers' exposures to Cr(VI) in air that are easier to control to the current REL than categories (3) and (4), (3) those with workers' exposures to Cr(VI) in air that are moderately difficult to control to the current REL, and (4) those exposures that are most difficult to control to the existing REL. This evaluation has not been updated to consider the recommended new REL of 0.2 μg/m³. It appears from NIOSH's statements that the relative difficulty for the industry to control exposures to the current REL of 1 μg/m³ will be the same as that to control to the proposed REL of 0.2 μg/m³. However, from inspection of these data, it is evident that, even though some categories of workers experienced minimal exposures or exposures that were easily controlled to the current REL of 1 μg/m³, none of the four categories can meet the new REL of 0.2 μg/m³. This has significant implications for medical monitoring, because NIOSH recommends monitoring for all workers where exposures exceed the REL or where exposures are unknown. Further, throughout the risk management discussion, references are made to the fact that some exposures will meet the REL, but it may be difficult for others. In reality, it will be virtually impossible for almost all industries and exposures to meet the newly proposed REL.

5 Supplemental information is available regarding dose response for dermal exposures and elicitation of allergic contact dermatitis.

The Criteria Document has been in preparation for more many years, and it seems evident that some of the discussion is dated and does not reflect information that is currently available in the scientific or regulatory literature. For example, the discussion of dermal effects states that there are no dose-response data for occupational exposures (Criteria Document, p. 58). While that is true, there *are* dose-response data that can be used to assess occupational exposures, and the U.S. EPA Office of Pesticide Programs has recently used it to evaluate exposures to treated wood (Proctor et al. 2006a,b). The studies by Proctor et al. were conducted in human subjects allergic to Cr(VI), using repeated, open application of test solutions containing Cr(VI). They studied two different types of Cr(VI) compounds—potassium dichromate, commonly used for studying environmental exposures, and acid copper chromate (ACC), a wood pesticide. In their technical reports that were submitted to EPA's Office of Pesticide Programs, Proctor et al. reported a clear dose-response effect for the occurrence of allergic contact dermatitis with increasing dose of Cr(VI) (as mass of Cr(VI) per unit area of skin). Proctor et al. (2006a,b) also performed dose-response modeling of the data obtained in these studies using EPA's Benchmark Dose software and reported minimum elicitation thresholds for Cr(VI)-induced allergic contact dermatitis (i.e., the minimum dermal dose of Cr(VI) required daily to elicit allergic skin reactions in sensitized individuals on repeated exposure). It is noteworthy that the study methodology of repeated, open applications is not only representative of community or environmental exposures to Cr(VI), but is also typical of occupational exposures. This is in contrast to other studies that have used occlusive dermal exposures to Cr(VI) using patch tests, which are not representative of real-life exposures (Nethercott et al. 1994).

Finally, in several places, the document misstates the literature or does not provide a complete discussion. Exponent has identified a few areas in the Criteria Document that lack a complete and current discussion or are inaccurate, but this should not be considered an inclusive list:

- **Page 8:** Provides a list of industries and operations that are associated with Cr(VI) exposure. However, the summary does not mention wood treating or construction, the latter of which involves exposure by contact with wet cement.

- **Page 40:** Section 4.1.1.1.1 discusses the North Carolina chromate production worker study by Pastides et al. (1994) but does not include the update by Luippold et al. (2005).

- **Page 43:** In the first paragraph, Mancuso is cited as Mancuso et al., but Mancuso is the sole author of that study. Also in that paragraph, it should be clarified that exposures occurring at Castle Hayne were included in the exposure reconstruction for Painesville workers (Proctor et al. 2004).

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